IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
Allan L. Louderback	Docket: ALL001
Serial No.: 10/661,329	Art Unit:
Filed: September 12, 2003	Examiner:
For: AN AUGMENTED SOLVENT/DETERGENT METHOD FOR INACTIVATING ENVELOPED AND NON-ENVELOPED VIRUSES	

RELATED ART/INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Sir:

Attached is a set of four sheets of replicated PTO-1449 forms, for the current Related Art/Information Disclosure Statement, utilized by the United States Patent Office. The Applicant does not believe that the indicated related art is particularly germane and certainly such does not anticipate or make obvious the invention of the above-identified application. Applicant distinguishes the related art patents and other publications from the present invention later in this document.

To the best of his recollection, the Applicant is not aware of any further patent or publication which might be deemed relevant. Restated, so far as the Applicant is able to presently recall, he is not aware of any related art patents or publications believed to be germane in any way to the above-

identified application other than the patents mentioned below and said patents and publications are only of general interest.

Patents

U.S. Patent 4,305,871 discloses a heat treatment process for inactivation of proteins.

U.S. Patent 4,314,997 discloses a method for purifying plasma protein products utilizing addition of an amphiphile to inactivate Hepatitis B and C.

U.S. Patent 4,315,919 discloses a method for depyrogenating biological and pharmaceutical products by prolonged contact with a solution or suspension of non-denaturing amphiphile.

U.S. Patent 4,412,985 discloses depyrogenation using an amphiphile (detergent).

U.S. Patent 4,481,189 discloses sterilization of plasma and killing of Hepatitis B and C (non A/non-B) and removal thereof. Note discussion of prior art wherein it is stated that crosslinks to protein is effected - implying such treatment would ruin the protein.

U.S. Patent 4,591,505 is a division of U.S. Patent 4,481,189.

U.S. Patent 4,764,369 discloses killing lipid coated viruses (enveloped) removal of di/tri alkyl phosphates. Also prior art avers formaldehyde will cause crosslinking to protein.

U.S. Patent 4,833,165 discloses Sterilization of washed red blood cells with formaldehyde/phenol and removal of sterilizing agent by washout procedure.

U.S. Patent 4,909,940 discloses S/D treatment using halogenated hydrocarbons and later removal of detergent.

U.S. Patent 5,094,960 discloses removal of lipid soluble chemicals with resin columns.

U.S. Patent 5,120,649 discloses photo-inactivation of lipid enveloped viruses in blood.

U.S. Patent 5,186,945 discloses removal of CMV viruses from plasma with another chemical plus detergent.

U.S. Patent 5,648,472 discloses a process for preparing virus inactivated immunoglobulin solutions suitable for intravenous application. In particular, see Abstract and Claim 1.

U.S. Patent 6,372,216 discloses a method of producing specific immunoglobulin to block HCV infection.

U.S. Patent 6,468,733 discloses a method for removal of detergents from S/D treated material by a resin composed of silicon beads and filtering.

U.S. Patent 6,514,987 discloses frangible compounds which react with nucleic acid of viruses to form breakdown products.

Publications

AGER, A.; ANDERSON, SL; LOUDERBACK AL; MILHOUS, WK; Formaldehyde/Detergent Solution Prevents Blood Borne Transmission of [Plasmaodium] Infection in a Mouse Model, *American Society of Tropical Medicine and Hygiene,* Abstract Submission Form, Annual Meeting, 1991 discloses a formaldehyde detergent study.

EHUD BEN-HUR, BERNARD HOROWITZ, Virus Inactivation in Blood, Editorial Review, *AIDS 1996, 10:1183-1190,* Rapid Science Publishers ISSN 0269-9370 discloses inactivation of viruses in blood, see page 1183 and Table 2, page 1187.

CHEN, SX; HAMMOND, DJ; LANG, JM; LEBING, WR; Purification of α_1 Protinase Inhibitor from Human Plasma Fraction IV-1 by Ion Exchange Chromatography; *Vox Sanguinis,* 1998:74(4): 232-241 discloses purification of biological product using ion exchange chromatography, see Abstract and page 233 (materials and methods).

CHEN, SX; HAMMOND, DJ; KLOS, AM; WOOD, DW; WYDICK, JE; LEBING, WR; Chromatography Purification of human α_1 Proteinase Inhibitor from Dissolved Cohn Fraction IV-1 Paste; Journal of Chromatography A. 800 (2) (1998); 207-218 discloses two independent viral inactivation steps used to produce a safer biological product, see Abstract, page 208 (end of second column) and page 209, section 2.

HIGHSMITH, F; XUE, H; CHEN, X; BENADE, L; OWENS, J; SHANBROM, E; DROHAN, W; Iodine-mediated Inactivation of Lipid- and Nonlipid-enveloped Viruses in Human Antithrombin III Concentrate; Blood, Volume 86, No. 2 (July 18, 1995); pages 791-796 discloses Iodine treatment to remove non-enveloped viruses, see Abstract and page 792.

HIGHSMITH, FA; XUE, H; CAPLE, M; WALTHALL, B; DROHAN, WN, SHANBROM, E; Inactivation of Lipid-Enveloped and Non-lipid-enveloped Model Viruses in Normal Human Plasma by Crosslinked Starch-iodine; Plasma Derivatives Department, Holland Laboratory, American Red Cross, Rockville, Maryland, and Irvine Scientific Incorporated, Santa Ana, California; received for publiction Aug. 26, 1993, revised Nov. 16, 1993 and accepted Nov. 22, 1993; published in Transfusion, 1994; Volume 34, No. 4, see, in particular, Abstract and Materials and Methods, page 323.

HIGHSMITH, FA; CAPLE, M; WALTHALL, B; SHANBROM, E; DROHAN, WN; Viral Inactivation of Vesicular Stomatitis Virus in Normal Human Serum by Cross-Linked Polyvinylpyrrolidone; The Journal of Infectious Diseases, 1993;167:1027-33, published by The University of Chicago discloses a different viral sterilization chemical (see Abstract).

HOROWITZ, B; PRINCE, AM; HAMMAN, J; WATKLEVICZ,C; Viral Safety of Solvent/Detergent-treated Blood Products; Blood Coagul. Fibrinolysis. 1994 Dec; 5 Suppl 3: S21-28. See Abstract for

safety of S/D products; page S22 for viral safety in formal clinical trials and Tables 1 and 2.

HOROWITZ, B; Pathogen Inactivated Transfusion Plasma: Existing and Emerging Methods, a proceedings paper from Vox Sanguinis 2002: 83, (Suppl. 1): 429-436, see introduction (page 429) and Table 5 (page 431).

HOROWITZ, B; BEN-HUR, E; Efforts in Minimizing Risk of Viral Transmission through Viral Inactivation; The Finish Medical Society Duodecim, Ann. Med. 2000, 32: 475-484, proposal for light -activatable compounds to sterile blood products; UV-C irradiation on blood components, see Abstract, page 478 and pages 479-81.

HOROWITZ, B; LAZO, A; GROSSBERG, H; PAGE, G; LIPPIN, A; SWAN, G.; Virus Inactivation by Solvent/Detergent Treatment and the Manufacture of SD-Plasma; Vox Sanguinis, Lunch Symposium Paper; Vox Sang. 1998, 74, Suppl. 1;: 203-206, see abstract (preparation SD plasma product) and Table 2 (double viral elimination steps).

HOROWITZ, B; PRINCE, AM; HAMMAN, J; WATKLEVICZ, C; Viral Safety of Solvent/Detergent-treated blood products; Blood Coagulation and Fibrinolysis, 5(3), S21-S28; copyrighted by Rapid Communications of Oxford, Ltd.; see Abstract, subjects: S/D safety and sterilizing enveloped viruses and Tables 1 and 2.

KORNEYEYA, M; HOTTTA, J; LEBING, W; ROSENTHAL, RS; FRANKS, L; PETTEWAY, SR Jr.; Enveloped Virus Inactivation by Caprylate: a

Robust Alternative to Solvent-Detergent Treatment in Plasma Derived Intermediates; Biologicals 2002, Jun; 30(2): 153-62 discloses enveloped virus inactivation without S/D treatment. (See Abstract)

LEBING, WR; HAMMOND, DJ; WYDICK, JE III; BAUMBACH, GA; A Highly Purified Antithrombin III Concentrate Prepared from Human Plasma Fraction IV-1 by Affinity Chromatography; Vox Sanguinis, Vox Sang., 1994; 67(2): 117-124 discloses viral inactivation by heating then using affinity chromatography to purify, see page 118 and Methods, second paragraph. Also, see Abstract.

LEBING, W; REMINGTON, KM; SCHREINER, C; PAUL, I; Properties of a New Intravenous Immunoglobulin (IGIV-C, 10%) Produced by Virus Inactivation with Caprylate and Column Chromatography; copyright Blackwell Publishing, Ltd., Vox Sanguinis (2003): 84 (3), 193-201; provides background, see Results and Conclusion, column 1, page 193 - Table 4 plus 194 (Manufacturing Process).

LEE, DC; STENLAND, CJ; MILLER JLC; CAI, K; FORD, EK; GILLIGAN, KJ; HARTWELL, RC; TERRY, JC; RUBENSTEIN, R; FOURNEL, M; PETTEWAY SR Jr.; A Direct Relationship between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity during the Purification of Plasma Proteins; *Transfusion*, 2001: 41(4): 449-455, provides background, results and conclusions, see page 449, column 1 and page 452 (Tables 1 and 2).

LOUDERBACK, A; A Protocol for Sterilization of Blood for Transfusion; Oral presentation at the 5th National Forum on AIDS, Hepatitis and other Blood Borne Diseases; CDC Meeting, Atlanta, GA on March 30, 1992, provides a proposal for use of formaldehyde for sterilization of blood for transfusion.

LOUDERBACK, A; Sterilization of Red Blood Cells for Transfusion; Speech at 45th AABB Meeting in San Francisco, November 11, 1992; provides background on using formaldehyde to sterilize blood.

MILLER. JLC; PETTEWAY, SR Jr; LEE, DC; Ensuring the Pathogen Safety of Intravenous Immunoglobulin and Other Human Plasma-derived Therapeutic Proteins; Journal of Allergy Clinical Immunology, October 2001 V. 108, pages S91-4; discloses two viral inactivation steps plus Figure 1.

ROBINSON, S; SCHWINN, H; JOSIC, D; NUR, I; STRADLER, M; BAL, F; GEHRINGER, W; SCHÜTZ, R; Development and Biochemical Characterization of a Double-virus-inactivated Factor VIII Preparation, *Blood Coagulation and Fibrinolysis, Vol 6, Suppl. 2, 1995, copyrighted by Rapid Science Publishers*, pages S40-47, discloses development of a second heat treatment in addition to S/D to remove viruses, see, in particular, page S40 on development.

SCHWINN, H; STADLER, M; JOSIC, DJ; BAL, F; GEHRINGER, W; NUR, I; SCHÜTZ, R; A Solvent/Detergent Treated, Pasteurised and

Highly Purified Factor VIII Concentrate; Arzneim.-Forsch./Drug Res. 44(I), Nr. 2 (1994)pages 188-191; discloses S/D treatment for enveloped viruses to make factor VIII concentrate with a second treatment of heat to remove other viruses, see page 189, sections 2 and 3 for heat treatment process.

STENLAND, CJ; LEE, DC; BROWN, P; PETTEWAY SR Jr.; RUBENSTEIN, R; Partitioning of Human and Sheep Forms of the Pathogenic Prion Protein during the Purification of Therapeutic Proteins from Human Plasma, Transfusion, Volume 42, November 2002: 1497-1500. See Background, Results and Conclusion, see page 1497, column 1 and page 1499, table 1.

TREJO, SR; HOTTA, JA; LEBING, W; STENLAND, C; STORMS, RE; LEE, DC; PETTEWAY, LS Jr.; REMINGTON, KM; Evaluation of Virus and Prion Reduction in a New Intravenous Immunoglobulin Manufacturing Process; Vox Sanguinis (2003) 84, 176-187, copyrighted by Blackwell Publishing, Ltd. See Background, Results and Conclusion; also see page 176; a new IGG manufacturing process (Figure 1 - page 178) and results (pages 180-181).

PRINCE, AM; Blood Products; *Nature. 1996 Jan 4; 379 (6560):14.* Article concerns a response about heat treatment to remove viruses.

CAI, K; MILLER, JL; STENLAND, CJ; GILLIGAN, KJ; HARTWELL, RC; TERRY, JC; EVANS-STORMS, RB; RUBENSTEIN, R; PETEWAY, SR Jr.; LEE, DC; Solvent-dependent Precipitation of Prion Protein.

Biochimica et Biophysica. Acta. 2002 May 20; 1597(1): 28-35. See Abstract plus page 32 (Figure 4) and Page 33 (Figures 5 and 6).

While the Applicant has presented his understanding and reasonable interpretation of the PTO-1449 patents and prior practices in the art, it is respectfully requested the Examiner make an independent review to independently determine the extent to which the prior practices and enclosed patents are deemed to be relevant, if at all, to the presently claimed invention of the above-identified application.

Respectfully submitted,

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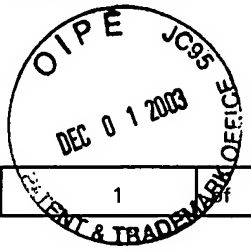
Substitute for form 1449A/PTO (Replication)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT



Complete if Known	
Application Number	10/661,329
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First Named Inventor	Allan L. Louderback
Art Unit	
Examiner Name	
Sheet 1 of 4	Attorney Docket Number ALL001

U.S. PATENT DOCUMENTS

Examiner Initials	Item	Document Number Number - kind code (if known)	Patent Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	01	4,305,871	12-15-81	Shanbrom	Abstract, Example 1, Claim 1
	02	4,314,997	02-09-82	Shanbrom	Abstract, First paragraph following Description of Invention, Claim 1
	03	4,315,919	02-16-82	Shanbrom	Abstract, Claim 1
	04	4,412,985	11-01-83	Shanbrom	Abstract, Claim 1
	05	4,481,189	11-06-84	Prince	Abstract, See first paragraph of Discussion of Prior Art eighth paragraph of same section
	06	4,591,505	05-27-86	Prince	Abstract, Division of 4,481,189
	07	4,764,369	08-16-88	Neurath, et al.	See abstract, prior art discussion
	08	4,833,165	05-23-89	Louderback	See Details of Invention, Claim 1
	09	4,909,940	03-20-90	Horowitz	Abstract, Background, Claim 1
	10	5,094,960	03-10-92	Bonomo	Abstract, Claim 1
	11	5,120,649	06-09-92	Horowitz, et al.	Abstract, Claim 1
	12	5,186,945	02-16-93	Shanbrom	See Abstract, Claim 1
	13	5,648,472	07-15-97	Gehringer, et al.	See Abstract, Claim 1
	14	6,372,216	04-16-02	Piazza	See Abstract, See last paragraph before claims
	15	6,468,733	10-22-02	Nur, et al.	See Abstract, Claim 1
	16	6,514,987	02-04-2003	Cook, et al.	See Abstract, Claim 1

FOREIGN PATENT DOCUMENTS

		None				

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	#	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue numbers, publisher, city and/or county where published	
	01	AGER, A.; ANDERSON, SL; LOUDERBACK AL; MILHOUS, WK; Formaldehyde/Detergent Solution Prevents Blood Borne Transmission of [Plasmaodium] Infection in a Mouse Model, *American Society of Tropical Medicine and Hygiene,* Abstract Submission Form, Annual Meeting, 1991	
	02	EHUD BEN-HUR, BERNARD HOROWITZ, Virus Inactivation in Blood, Editorial Review, *AIDS 1996, 10:1183-1190,* Rapid Science Publishers ISSN 0269-9370.	
	03	CHEN, SX; HAMMOND, DJ; LANG, JM; LEBING, WR; Purification of α_1 Protinase Inhibitor from Human Plasma Fraction IV-1 by Ion Exchange Chromatography; *Vox Sanguinis,* 1998: 74(4): 232-241.	
	04	CHEN, SX; HAMMOND, DJ; KLOS, AM; WOOD, DW; WYDICK, JE; LEBING, WR; Chromatography Purification of human α_1 Proteinase Inhibitor from Dissolved Cohn Fraction IV-1 Paste; Journal of Chromatography A. 800 (2) (1998): 207-218.	
	05	HIGHSMITH, F; XUE, H; CHEN, X; BENADE, L; OWENS, J; SHANBROM, E; DROHAN, W; Iodine-mediated Inactivation of Lipid- and Nonlipid-enveloped Viruses in Human Antithrombin III Concentrate; *Blood,* Volume 86, No. 2 (July 18, 1995); pages 791-796	
	06	HIGHSMITH, FA; XUE, H; CAPLE, M; WALTHALL, B; DROHAN, WN, SHANBROM, E; Inactivation of Lipid-Enveloped and Non-lipid-enveloped Model Viruses in Normal Human Plasma by Crosslinked Starch-iodine; *Plasma Derivatives Department, Holland Laboratory, American Red Cross, Rockville, Maryland, and Irvine Scientific Incorporated, Santa Ana, California; received for publication Aug. 26, 1993, revised Nov. 16, 1993 and accepted Nov. 22, 1993; published in Transfusion*, 1994; Volume 34, No. 4, pages 322-327.	
	07	HIGHSMITH, FA; CAPLE, M; WALTHALL, B; SHANBROM, E; DROHAN, WN; Viral Inactivation of Vesicular Stomatitis Virus in Normal Human Serum by Cross-Linked Polyvinylpyrrolidone; *The Journal of Infectious Diseases, 1993;167:1027-33, published by The University* of Chicago.	
	08	HOROWITZ, B; PRINCE, AM; HAMMAN, J; WATKLEVICZ,C; Viral Safety of Solvent/Detergent-treated Blood Products; *Blood Coagul. Fibrinolysis. 1994 Dec; 5 Suppl 3: S21-28.* See Abstract for safety of S/D products; page S22 for viral safety in formal clinical trials and Tables 1 and 2.	

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	09	HOROWITZ, B; Pathogen Inactivated Transfusion Plasma: Existing and Emerging Methods, a proceedings paper from *Vox Sanguinis (Vox Sang 2002: 83, (Suppl. 1): 429-436*	
	10	HOROWITZ, B; BEN-HUR, E; Efforts in Minimizing Risk of Viral Transmission through Viral Inactivation; *The Finish Medical Society Duodecim, Ann. Med. 2000, 32: 475-484.*	
	11	HOROWITZ, B; LAZO, A; GROSSBERG, H; PAGE, G; LIPPIN, A; SWAN, G.; Virus Inactivation by Solvent/Detergent Treatment and the Manufacture of SD-Plasma; *Vox Sanguinis, Lunch Symposium Paper; Vox Sang. 1998, 74, Suppl. 1;: 203-206.*	
	12	HOROWITZ, B; PRINCE, AM; HAMMAN, J; WATKLEVICZ, C; Viral Safety of Solvent/Detergent-treated blood products - ABSTRACT; *Dev Biol Stand. 1993;81: 147-161.*	
	13	KORNEYEYA, M; HOTTTA, J; LEBING, W; ROSENTHAL, RS; FRANKS, L; PETTEWAY, SR Jr.; Enveloped Virus Inactivation by Caprylate: a Robust Alternative to Solvent-Detergent Treatment in Plasma Derived Intermediates; *Biologicals, 2002 Jun; 30(2): 153-62.*	
	14	LEBING, WR; HAMMOND, DJ; WYDICK, JE III; BAUMBACH, GA; A Highly Purified Antithrombin III Concentrate Prepared from Human Plasma Fraction IV-1 by Affinity Chromatography; Vox Sanguinis, Vox Sang., 1994; 67(2): 117-124.	
	15	LEBING, W; REMINGTON, KM; SCHREINER, C; PAUL, I; Properties of a New Intravenous Immunoglobulin (IGIV-C, 10%) Produced by Virus Inactivation with Caprylate and Column Chromatography; copyright Blackwell Publishing, Ltd., Vox Sanguinis (2003): 84(3), 193-201.	
	16	LEE, DC; STENLAND, CJ; MILLER JLC; CAI, K; FORD, EK; GILLIGAN, KJ; HARTWELL, RC; TERRY, JC; RUBENSTEIN, R; FOURNEL, M; PETTEWAY SR Jr.; A Direct Relationship between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity during the Purification of Plasma Proteins; *Transfusion*, 2001: 41(4): 449-455.	
	17	LOUDERBACK, A; A Protocol for Sterilization of Blood for Transfusion; Oral presentation at the 5th National Forum on AIDS, Hepatitis and other Blood Borne Diseases; CDC Meeting, Atlanta, GA on March 30, 1992.	

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	18	LOUDERBACK, A; Sterilization of Red Blood Cells for Transfusion; *Speech at 45th AABB Meeting in San Francisco, November 11, 1992.*	
	19	MILLER. JLC; PETTEWAY, SR Jr; LEE, DC; Ensuring the Pathogen Safety of Intravenous Immunoglobulin and Other Human Plasma-derived Therapeutic Proteins; *Journal of Allergy Clinical Immunology, October 2001 V. 108, pages S91-4 (Figure S92).*	
	20	ROBINSON, S; SCHWINN, H; JOSIC, D; NUR, I; STRADLER, M; BAL, F; GEHRINGER, W; SCHUTZ, R; Development and Biochemical Characterization of a Double-virus-inactivated Factor VIII Preparation, *Blood Coagulation and Fibrinolysis, Vol 6, Suppl. 2, 1995, copyrighted by Rapid Science Publishers; pages S40-47.*	
	21	SCHWINN, H; STADLER, M; JOSIC, DJ; BAL, F; GEHRINGER, W; NUR, I; SCHÜTZ, R; A Solvent 1 Detergent Treated, Pasteurised and Highly Purified Factor VIII Concentrate; *Arzneim.-Forsch./Drug Res. 44(I), Nr. 2 (1994) pages 188-191 (English and German).*	
	22	STENLAND, CJ; LEE, DC; BROWN, P; PETTEWAY SR Jr.; RUBENSTEIN, R; Partitioning of Human and Sheep Forms of the Pathogenic Prion Protein during the Purification of Therapeutic Proteins from Human Plasma, *Transfusion, Volume 42(11), November 2002, pages 1497-1500.*	
	23	TREJO, SR; HOTTA, JA; LEBING, W; STENLAND, C; STORMS, RE; LEE, DC; PETTEWAY, LS Jr.; REMINGTON, KM; Evaluation of Virus and Prion Reduction in a New Intravenous Immunoglobulin Manufacturing Process; *Vox Sanguinis (2003) 84, 176-187, copyrighted by Blackwell Publishing, Ltd.*	
	24	PRINCE, AM; Blood Products; *Nature. 1996 Jan 4; 379 (6560):14.* See entire article	
	25	CAI, K; MILLER, JL; STENLAND, CJ; GILLIGAN, KJ; HARTWELL, RC; TERRY, JC; EVANS-STORMS, RB; RUBENSTEIN, R; PETEWAY, SR Jr.; LEE, DC; Solvent-dependent Precipitation of Prion Protein. *Biochimica et Biophysica Acta. 2002 May 20; 1597(1): 28-35.* See Abstract plus page 32 (Figure 4) and Page 33 (Figures 5 and 6).	

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